

REMARKS

Applicant respectfully requests reconsideration. Claims 180-191 were previously pending in this application. Claims 180 and 189 have been amended. Support for the amendments can be found throughout the specification as filed, for example, on page 18, lines 23-25, and Table 1. New claims 192-206 have been added. Support for the new claims can be found throughout the specification as filed, for example, on page 9, lines 29-31; page 16, lines 23-24; page 28, lines 4-5; page 33, lines 24-26; page 34, lines 7-9; and page 59, lines 19-33. As a result, claims 180-206 are pending for examination with claims 180, 189, 192, 198, 201 and 205 being independent claims. No new matter has been added.

Objections to the Specification

The Examiner objected to the specification because it contains embedded hyperlinks and/or other forms of browser-executable code. Applicant has amended the specification to remove embedded hyperlinks and/or other forms of browser-executable code. The objection is now believed to be moot.

Accordingly, withdrawal of the objection is respectfully requested.

Rejections under 35 U.S.C. §112

The Examiner rejected claim(s) 180-191 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for isolated polypeptides comprising the sequence set forth in SEQ ID NO: 55, allegedly does not reasonably provide enablement for just any polypeptide comprising just any polypeptide fragment of SEQ ID NO: 55 that is at least 8 amino acids in length. According to the Examiner, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the claimed invention in manners disclosed in the specification.

Applicant respectfully traverses. "In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention." MPEP 2164.04. The Examiner has not met this burden.

"The invention that one skilled in the art must be enabled to make and use is that defined by the claims." MPEP 2164. In the instant case, the claims are directed to certain isolated polypeptides, as well as to compositions and kits comprising the same. While not challenging

that one of ordinary skill in the art is enabled to produce such polypeptides, the Examiner has argued that one of ordinary skill in the art is not enabled to use them. Applicant strongly disagrees.

The instant specification teaches that the isolated polypeptides of the claims have a number of uses, including, but not limited to, the identification of antibodies reactive to a human sarcoma-associated antigen, the sequence of which is set forth as SEQ ID NO: 55, in a sample as well as the production of antibodies specific for such antigen. For example, with the teaching of the sequence set forth as SEQ ID NO: 55 in combination with the techniques for antibody production provided in the instant specification or otherwise known to those of ordinary skill in the art, one of ordinary skill in the art is enabled to use the claimed polypeptides to produce antibodies specific to the antigen of SEQ ID NO: 55. As evidenced by basic antibody texts, such as that of Harlow and Lane (1988), it was clearly routine in the art at the time of the filing of the instant application to use full-length polypeptides or fragments thereof to generate antibodies specific to an antigen of a known sequence.

The Examiner has argued that the instant specification fails to disclose which of the polypeptides of the claims provide epitopes that are “exposed” on the antigen. However, even if, *arguendo*, the Examiner’s assertion is true, the failure to disclose which of the polypeptides provide exposed epitopes does not negate the enablement of the claims for at least three reasons. First, one of ordinary skill in the art, even without knowledge of the exposed epitopes, can use the polypeptides of the claims and determine with only routine experimentation whether or not the antibodies elicited are specific to the antigen in native form. In addition, Applicant respectfully reminds the Examiner that even if the claims encompass inoperative embodiments, the standard for enablement is whether or not one of ordinary skill in the art is able to determine which embodiments are operative or inoperative with no more than routine experimentation. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984). Second, one of ordinary skill in the art is able to determine the polypeptides of the claims that are or include exposed epitopes with no more than routine experimentation. The Examiner is respectfully reminded that the amount of experimentation is not a factor in assessing enablement. Third, antibodies against non-exposed epitopes, may be used, for example, to detect the polypeptide of SEQ ID NO: 55 under denaturing conditions (e.g., in immunoblotting). The

Examiner's assumption that only antibodies that bind exposed epitopes would be used by one of ordinary skill in the art is not correct.

The Examiner has also argued that Dumas highlights the unpredictability of using the claimed polypeptides as the polypeptide, in total, of Dumas shares low homology with the disclosed sarcoma-associated antigen. Applicant disagrees with this assertion. First, the polypeptide, to which the Examiner refers, is not a polypeptide of at least Applicant's amended claims, and, therefore, is not germane to the enablement assessment of the polypeptides of such claims. Second, even if the claims, *arguendo*, encompass inoperative embodiments, the test for enablement is whether or not more than routine experimentation is required to identify the inoperative embodiments. Applicant asserts that routine experimentation is all that is required.

Lastly, Applicant notes that when a compound or composition is not limited by a recited use, such as in the instant claims, any enabled use that would reasonably correlate with the entire scope of a claim is sufficient to preclude a rejection for nonenablement based on how to use. MPEP 2164.01. Moreover, "when multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use." *Id.* (emphasis added). The Examiner has failed to set forth such an explanation and, therefore, the required burden for establishing an enablement rejection has not been met.

In view of the foregoing, withdrawal of the rejection of claims 180-191 under 35 U.S.C. §112 is respectfully requested.

Rejections Under 35 U.S.C. §102

The Examiner rejected claims 180-182 and 189-191 under 35 U.S.C. §102 as allegedly being anticipated by Dumas et al (EP 1033401A2).

Applicant respectfully traverses. However, without conceding the correctness of the Examiner's rejection and in the interest of expediting prosecution, Applicant has amended claim 180 to recite that the isolated polypeptide consists of a sequence as set forth as SEQ ID NO: 55 or a fragment thereof that is at least 8 amino acids in length. The isolated polypeptide of Dumas, cited by the Examiner, does not consist of a sequence as set forth as SEQ ID NO: 55 or a fragment thereof that is at least 8 amino acids in length.

Accordingly, withdrawal of the rejection of claims 180-182 and 189-191 under 35 U.S.C. §102 is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. L0461.70156US00.

Respectfully submitted,

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